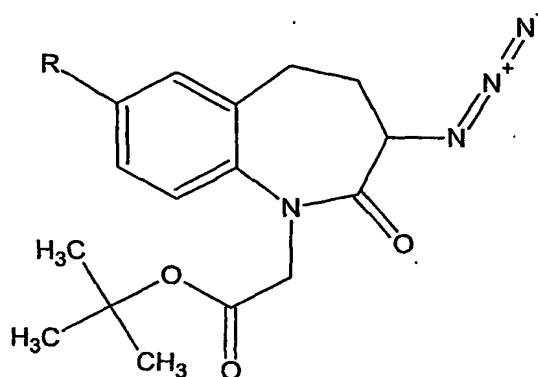


We Claim:

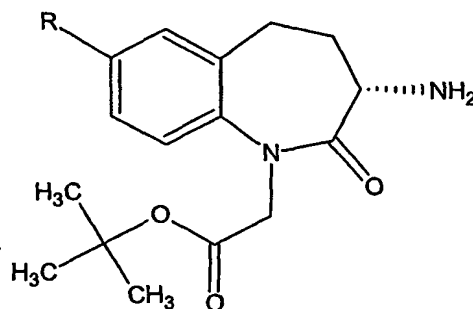
1. A process for preparation of highly pure 3-amino t-butyl ester of Formula II wherein R is hydrogen having no detectable quantity of impurity 7-bromo-3-amino t-butyl ester of Formula IIa, wherein R is Br, wherein the process comprises:

a) hydrogenating 3-azido t-butyl ester of Formula IV containing up to about 8% of 7-bromo-3-azido t-butyl ester of Formula IVa in presence of a noble metal catalyst; and



FORMULA IV (R = H)
FORMULA IVa (R = Br)

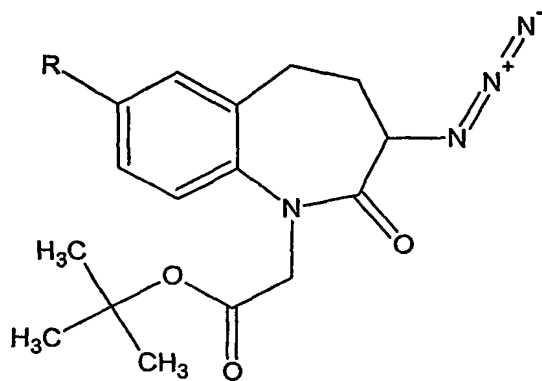
b) isolating highly pure racemic 3-amino t-butyl ester of Formula II having no detectable quantity of 7-bromo-3-amino t-butyl ester of Formula IIa



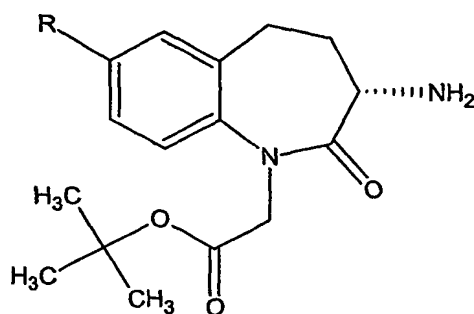
FORMULA II (R = H)
FORMULA IIa (R = Br)

2. A process according to claim 1 wherein the noble metal catalyst is selected from a group comprising of palladium on carbon, platinum oxide, platinum black, palladium acetate and rhodium on carbon.

- 1 3. A process according to claim 2 wherein the noble metal catalyst is palladium on
2 carbon.
- 1 4. A process according to claim 1 wherein hydrogen gas is used in hydrogenation.
- 1 5. A process according to claim 1 wherein a source of hydrogen gas is used in the
2 reaction.
- 1 6. A process according to claim 5 wherein the source of hydrogen is selected from a
2 group comprising ammonium formate, formic acid and alkali metal formate or
3 mixtures thereof.
- 1 7. The process according to claim 6 wherein the alkali metal formate is selected from
2 sodium formate or potassium formate.
- 1 8. A process according to claim 1 wherein the hydrogenation is carried out in
2 presence of an organic solvent.
- 1 9. A process according to claim 8 wherein organic solvent is selected from alkanols,
2 esters and cyclic ethers or mixtures thereof.
- 1 10. A process according to claim 9 wherein the organic solvents are selected from
2 methanol, ethanol, propanol, isopropanol, tetrahydrofuran, ethyl acetate,
3 diisopropyl ether or mixtures thereof.
- 1 11. A process according to claim 8 wherein organic solvent is formic acid or acetic
2 acid.
- 1 12. A process according to claim 1 wherein the hydrogenation is carried out at a
2 temperature of about 10 to about 60°C.
- 1 13. The process of claim 1, further comprising isolating the S-enantiomer of the
2 compound of Formula II by chiral resolution.
- 1 14. A process for preparation of highly pure 3-amino t-butyl ester of Formula II having
2 no detectable quantity of impurity 7-bromo-3-amino t-butyl ester of Formula IIa,
3 wherein the process comprises:
- 4 a) hydrogenating 3-azido t-butyl ester of Formula IV containing up to about 8%
5 of 7-bromo-3-azido t-butyl ester of Formula IVa in presence of Raney nickel to
6 get the racemic 3-amino t-butyl ester of Formula II containing up to about 8%
7 of 7-bromo-3-amino t-butyl ester of Formula IIa;



FORMULA IV (R = H)
FORMULA IVa (R = Br)

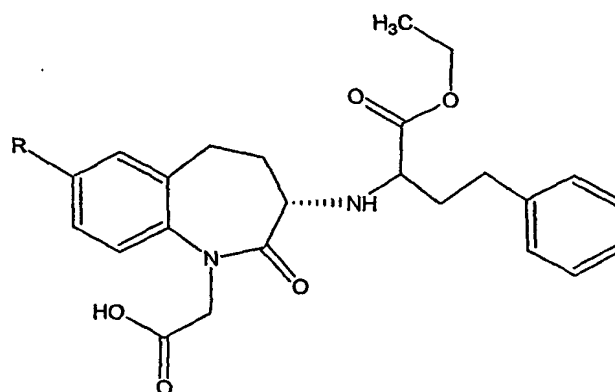


FORMULA II (R = H)
FORMULA IIa (R = Br)

- b) hydrogenating the product of step a) in the presence of a noble metal catalyst;
 and
 c) isolating highly pure racemic 3-amino t-butyl ester of Formula II having no detectable quantity of 7-bromo-3-amino t-butyl ester of Formula IIa.

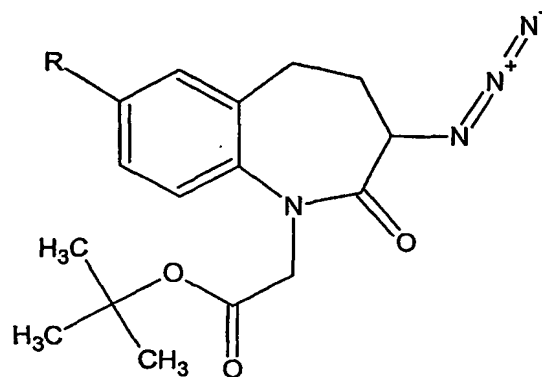
15. A process according to claim 14 wherein hydrogenation in step a) is carried out in an organic solvent.
16. A process according to claim 15 wherein the organic solvent comprises of an alcohol or a lower carboxylic acid.
17. A process according to claim 16 wherein an alcohol is methanol, ethanol, isopropanol or mixtures thereof.
18. A process according to claim 16 wherein a lower carboxylic acid is selected from formic acid or acetic acid or mixtures thereof.

- 1 19. A process according to claim 14 wherein the noble metal catalyst is selected from a
 2 group comprising of palladium on carbon, platinum oxide, platinum black,
 3 palladium acetate and rhodium on carbon.
- 1 20. A process according to claim 19 wherein noble metal catalyst is palladium on
 2 carbon.
- 1 21. The process of claim 14, further comprising isolating the S-enantiomer of the
 2 compound of Formula II by chiral resolution.
- 1 22. A process for preparation of highly pure benazepril of Formula I or a
 2 pharmaceutically acceptable salt, solvate and hydrate thereof, having no detectable
 3 quantity of 7-bromo analogue of Formula Ia, wherein the said process comprises of

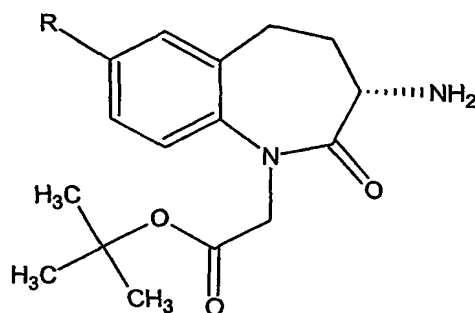


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 5 **FORMULA I (R = H)**
 6 **FORMULA Ia (R = Br)**

- 7 a) hydrogenating 3-azido t-butyl ester of Formula IV, optionally containing up to
 8 about 8% of 7-bromo-3-azido t-butyl ester of Formula IVa, in presence of a
 9 metal catalyst and isolating the racemic 3-amino t-butyl ester of Formula II
 10 which is optionally devoid of the corresponding 7-bromo-3-amino t-butyl ester
 11 of Formula IIa impurity;

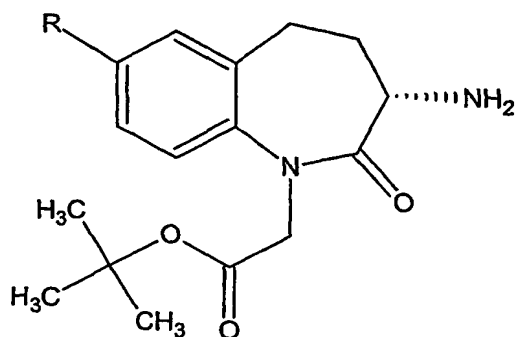


FORMULA IV (R = H)
FORMULA IVa (R = Br)

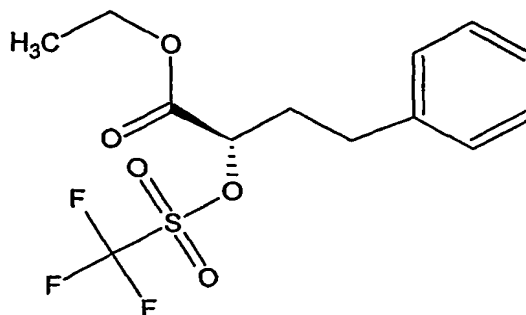


FORMULA II (R = H)
FORMULA IIa (R = Br)

- b) hydrogenating the racemic 3-amino t-butyl ester of Formula II, optionally containing up to about 8% of 7-bromo-3-amino t-butyl ester of Formula IIa, in presence of a noble metal catalyst to get highly pure racemic II having no detectable amount of 7-bromo ester of Formula IIa;
- c) converting the highly pure racemic 3-amino t-butyl ester of Formula II to the highly pure (S)- 3-amino t-butyl ester of Formula II by chiral resolution;
- d) condensing the highly pure (S)- 3-amino t-butyl ester of Formula II with Trifluoromethane sulphonic ester of ethyl (R)-2-hydroxy-4-phenylbutyrate of Formula III in presence of an organic solvent and a base to get highly pure compound of Formula I or physiologically acceptable salts, solvates or hydrates thereof.



FORMULA II (R = H)



FORMULA III

23. A process according to claim 22 wherein metal catalyst in step a) is selected from palladium on carbon, platinum oxide, platinum black, palladium acetate, rhodium on carbon or Raney nickel.
24. A process according to claim 22 wherein noble metal catalyst in step b) is selected from palladium on carbon, platinum oxide, platinum black, palladium acetate or rhodium on carbon.
25. A process according to claims 22 and 23 wherein step b) is not performed if in step a) metal catalyst is selected from palladium on carbon, platinum oxide, platinum black, palladium acetate and rhodium on carbon.
26. A process according to claims 22 and 23 wherein step b) is performed if in step a) metal catalyst used is Raney nickel.
27. A process according to claim 22 wherein step c) provides a tartarate salt of (S)-II which is then converted to (S)-II freebase.
28. A process according to claim 27 wherein the intermediate tartarate salt of S-II is purified by crystallization.
29. A process according to claim 22 wherein the organic solvent used in step d) is selected from chlorinated hydrocarbons.
30. A process according to claim 29 wherein chlorinated hydrocarbon is selected from chloroform, carbon tetrachloride, methylene chloride, ethylene bromide, ethylene chloride or mixtures thereof.
31. A process according to claim 22 wherein the base used in step d) is selected from pyridine and its derivatives, morpholine and its derivatives, trialkyl amines and cyclic amines or mixtures thereof.

- 1 32. A process according to claim 22 wherein intermediate compound VI is isolated
2 after completion of reaction between highly pure S-II and III.
- 1 33. A process according to claim 32 wherein the intermediate compound VI is further
2 converted to highly pure I by treatment with acid.
- 1 34. A process according to claim 33 wherein the acid used is mineral acid or an
2 organic acid.
- 1 35. A process according to claim 34 wherein the mineral acid is hydrochloric acid in
2 gaseous form or in the form aqueous solution.
- 1 36. A process according to claim 22 wherein the physiologically acceptable salt of I is
2 hydrochloride salt.
- 1 37. A highly pure compound of Formula II having no detectable quantity of IIa.
- 1 38. A highly pure benazepril of Formula I or physiologically acceptable salt, solvate
2 and hydrate thereof having no detectable quantity of Ia.
- 1 39. A process of preparation of benazepril of Formula I or physiologically acceptable
2 salt, solvate and hydrate thereof wherein highly pure compound of Formula II
3 having no detectable quantity of IIa is used as an intermediate.
- 1 40. A pharmaceutical compositions comprising highly pure benazepril of Formula I or
2 physiologically acceptable salt, solvate and hydrate thereof having no detectable
3 quantity of Ia along with a pharmaceutically acceptable carriers or diluents.
- 1 41. A method of antagonizing angiotensin-converting enzyme (ACE) wherein the said
2 method comprises of administering to a mammal in need thereof a therapeutically
3 effective amount of highly pure benazepril of Formula I or physiologically
4 acceptable salt, solvate and hydrate thereof having no detectable quantity of Ia.